

29 Reliability and validity study of the sweat conductivity test in a reference center in Rio de Janeiro

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This study evaluated the reliability and validity of the sweat conductivity test between July and September 2010. We included CF patients and clinical suspicion ones referred to sweat test after having signed the consent form approved by the Ethics Committee. Sweat conductivity tests were performed with the Macroduct system, Sweat-Chek Analyser and Gibson&Cooke (G&C) techniques. The cut points for diagnosis were ≥ 90 and ≥ 60 mmol/l, respectively. Reliability was verified by the comparison of the conductivity measures done in the same day on both arms of 81 patients. To validation, 129 conductivity measures were taken from the right arm (RA) and compared to the chloride (Cl^-) values found by G&C. In addition to the descriptive statistics, we estimated Pearson's r and Bland-Altman. We included 129 patients with median age of 52 months (mo), 55% female, 60.5% white and 99.2% residents of RJ. Among the 42 CF, median age was 117.5 mo (13–229), 61.9% female and 52.4% white. Among the suspected CF patients median age was 33 mo (1–211), 51.7% were female and 64.4% white. Mean conductivity on the RA was 68.41 (SD 46.49) and LA 66.88 (SD 43.52) mmol/l. Pearson's r was 0.97 and the mean differences 1.53 (SD 10.69) mmol/l (95% CI: -19.43 to 22.49). The mean conductivity on the RA of 129 patients was 70.17 (SD 45.6) and the mean Cl^- 36.75 (SD 37.58) mmol/l. Pearson's r was 0.85, and the characteristics of the test were sensitivity = 89%, specificity = 92%, PPV = 82.5% and NPV = 95.5%.

The sweat conductivity test should present higher sensitivity for CF screening in the general population. For the CF clinical suspicion patients it has been demonstrated to be an accurate diagnosis procedure.

30 Implementation of NPD in a reference center in Rio de Janeiro

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Between 2009 and 2010, we performed exams in volunteers who had signed the consent form approved by ethics committee. Were included exams which minimum stability of 30 seconds in the 4 phases: basal (A1), amiloride (A2), chloride free (B1) and isoproterenol (B2). The summary measures were described and compared by ANOVA and non-parametric tests and reproducibility verified by Pearson's r and Bland Altman. From the 127 exams, 64% (81) were performed on females mean age 28 years (SD 16) and median of 27 years (1 to 60), where 15% (19) on CF patients and 85% (108) on volunteers. The mean (SD) and median (range) were respectively 30 (10) and 30 (12–47) mV in CF and 14 (8) and 14 (2–45) mV in volunteers for the maximal basal nasal potential difference (PD_{max}); were 14 (8) and 11 (5–31) in CF and 7 (4) and 6 (0–22) in volunteers for delta amiloride (Δ_{amil}) and were 4 (6) and 5 (–11–13) in CF and 14 (7) and 12 (3–42) in volunteers for free chloride delta ($\Delta_{\text{free Cl}}$). The differences between the mean and median values were statistically significant with p values <0.0001 . The reliability analysis of repetitive measures of 22 volunteers revealed Pearson's r of 0.79 for PD_{max} and 0.75 for $\Delta_{\text{free Cl}}$, both with p values of <0.0001 and for the Bland-Altman method the differences were -1.9 (95% CI: -14–10) for PD_{max} and 2.5 (95% CI: -9.6–14.7) for $\Delta_{\text{free Cl}}$. The greater part of the observations was included in the $\pm 2\text{SD}$ interval of median difference. Besides the necessary correlations coming from changes in the technique, we can achieve more precision in the reproducibility increasing the number of examinations and increasing the control of all sources of variables.

31 Modified nasal catheter for measurement of nasal potential difference improves reproducibility

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Nasal potential difference (NPD) measurement reflects changes in chloride transport through respiratory epithelia of CF and non CF subjects. The limited NPD test reproducibility however hampers the measurement's usefulness as outcome parameter. We explored whether repeatability is improved by measuring over a larger contact area.

A catheter with a 360° contact area over 2 cm was designed. NPD was measured simultaneously with this large contact area catheter at 3 cm depth under the turbinate and the standard 8Fr side hole catheter on the nasal floor in the other nostril. NPD was repeated after a median of 2 days (range 1–60) in 20 subjects.

Correlation between repeated measurement for total chloride secretion was significantly better with the large contact than with the standard side hole catheter ($R=0.108$ vs -0.689 , $p=0.038$); within-subject variance (26.7 mV^2 vs 220.1 mV^2) and mean coefficient of variation (35.2% vs 59.7%, $p=0.042$) were lower. Power calculations for a clinical trial using change in total chloride secretion as primary endpoint favors the use of the large contact area catheter ($\text{nnt} = 20$ vs 40 for a correction to 33% of the chloride secretion in normal subjects). Measurements with the standard catheter resulted in more negative NPD during perfusion with Ringer ($13.5 \text{ mV} \pm 7.2 \text{ mV}$ vs $10.0 \text{ mV} \pm 4.4 \text{ mV}$, $p=.004$), larger amiloride response ($+8.0 \text{ mV} \pm 6.0 \text{ mV}$ vs $+4.8 \text{ mV} \pm 2.6 \text{ mV}$, $p=.003$), and larger total chloride secretion ($-21.5 \text{ mV} \pm 15.9 \text{ mV}$ vs $-14 \text{ mV} \pm 9.1 \text{ mV}$, $p=.011$).

NPD measurements over a larger contact area, have a better reproducibility than measurements done with the side hole catheter used routinely.

32 Adverse events (AE) in nasal potential difference (NPD) measurements under the inferior turbinate in healthy adults

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Objectives: To evaluate AE during and after NPD, comparing 2 NPD techniques. **Methods:** Healthy adults underwent NPD using (A) needle-calomel electrode or (B) Ag-AgCl electrode on abraded skin. Marquat® catheter (end-hole) was placed in the meatus inferior (MI) in both nostrils the same day. AE were checked during and 48 h after NPD procedure. 16 healthy adults underwent NPD. 8/16 had both tests (A+B), 7/16 only B and 1/16 only A. 3/9 with A had pain at needle insertion. 1/16 had throat pain at position 2 cm, despite catheter replacement. Sinusitis with headache appeared in 3/24 tests in 2 adults. One had sinusitis after A+B, the other had only B and refused A. In 6/15 NPD with B a crust was seen after skin abrasion. One subject with a swollen eye for 1 day after test B, had itchy cheek and chin after subsequent NPD in 1 nostril with A; 2nd nostril was not done for fear of an allergic reaction.

Discussion: NPD is considered not painful, but some AE were seen. Needle placement was more painful, but a crust was only seen with abrasion. Acute sinusitis post NPD was seen in 2 adults, known with chronic sinusitis. Misplacement of catheter in MM (entailing the sinus outflow) instead of MI could explain sinusitis by oedema due to catheter manipulation and high perfusion. A swollen eye after NPD can be due to catheter position at the ostium of the nasolacrimal duct, located in MI, where oedema or retrograde flow can lead to swelling of the eye. Itchy skin suggested allergic reaction on the solutions. Skin prick tests were doubtful for Ringer.

Conclusion: NPD catheter positioning in MI entails risks for AE. Catheter placement on the nasal floor might prevent above mentioned features.